

R E M A R K S

The Office Action of February 6, 2002, presents the examination of claims 1-4, 6-7, 9-18, 30-36, 40-41 and 43-44. Claims 1, 30, 32, and 36 are amended herein. No new matter is inserted into the application. A marked-up copy of the claims is attached hereto to show the changes made by this Reply.

Further, a new copy of all of the pending claims (as amended) is attached hereto. Applicants in particular draw the Examiner's attention to claim 35 of the pending claims. In the Supplemental Amendment filed on January 16, 2002, there was a typographical error in claim 35 wherein the phrase "or a cell thereof" was accidentally left out of the claim. Claim 35 as shown in the attached copy of the pending claims is correct.

*Claim Objections*

The Examiner objects to claim 1 for recitation of the phrase "capable of producing" and suggests replacement thereof with "produces." In response to the Examiner's remarks, Applicants amend the phrase to "which produces." Further, Applicants amend claims 30, 32, and 36 in the same manner. Thus, the instant objection is overcome.

***Rejection under 35 U.S.C. § 112, second paragraph***

The Examiner rejects claims 10, 14, 30, 32, and 36 under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Specifically, the Examiner states that the recitation of "the raffinose synthase gene" lacks antecedent basis. Applicants respectfully point out that the phrase "the raffinose synthase gene" was amended out of these claims in the Supplemental Amendment filed on January 16, 2002, as shown in the copy of the pending claims attached hereto. The Examiner is respectfully requested to withdraw the instant rejection.

***Rejection under 35 U.S.C. § 112, first paragraph***

The Examiner rejects claims 1-4, 7, 10-11, 14-16, 30-36, and 40-41 under 35 U.S.C. § 112, first paragraph for an alleged lack of written description in the specification. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Basically, the Examiner appears to assert that the claims are too broad for the amount of disclosure found in the specification. In making the instant rejection, the Examiner relies upon the holding of *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). However, Applicants wish to

point out at the very beginning that the facts of the present application are very different from the facts in *Lilly*.

First, the claim in *Lilly* encompassed all "mammalian" insulin genes, even though the specification only completely described a single gene (encoding rat insulin) and poorly described a process for obtaining additional insulin genes (plating clones, picking them and sequencing them to determine if the cDNA encoded an insulin gene).

In contrast, the present application describes a plurality of isolated nucleic acids which encode raffinose synthase (SEQ ID NOS:1, 3, 5 and 7) and furthermore provides description of a method for obtaining an isolated nucleic acid encoding raffinose synthase from any desired organism (or at least surveying the organism for the existence of the gene) by performing a PCR reaction with one or more of a number of upstream and downstream primers.

The function of the written description requirement is to assure that the inventor in fact had the claimed invention in his possession at that time the application was filed. See, Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement. 66 F.R. 1,099 (2001). In the instance of the *Lilly* case, it was clear that at the time the application was filed, the inventors did not possess the invention broadly. They had isolated but a single insulin gene, and that from a rat, an organism that was not really of

interest to the pharmaceutical industry, with the future desire to use human genes and gene products. The broad claim to genes encoding "mammalian" insulin was a bald attempt to extend the limited attainments of the inventors to cover the invention that was of real value.

On the other hand, in the present application the inventors have described four variant cDNAs, obtained from four different plant species, that encode proteins having the desired activity. The inventors have further provided examples of PCR primers and detailed description of how to use them to isolate additional examples of isolated DNA encoding raffinose synthase from other species. Working examples (7 and 9-11) of use of the PCR primers to perform such isolations are provided. This disclosure is much more than a "mere statement that [broadly claimed DNA] is part of the invention and reference to a potential method of isolating it." *Fiers v. Sugano*, 25 USPQ2d 1601 (Fed. Cir. 1993). This disclosure constitutes actual variants within the claimed genus and actual methods that can be used to find the next species within the genus. Furthermore, the demonstration of isolation of three additional species of cDNA within the scope of the claims, starting from a first one obtained by the inventors, establishes predictability of obtaining additional species.

The inventors have further provided description of an assay that can be used to determine if the protein encoded by any gene

isolated by the method of the Example in fact is a functional raffinose synthase. See, Example 2 at pp. 26 ff.

Clearly the present application "convey[s] the information that an application has invented the subject matter which is claimed." Thus, the rejection of claims 1-4, 7, 10-11, 14-16, 30-36, and 40-41 under 35 U.S.C. § 112, first paragraph, for alleged lack of adequate written description of the claimed invention, should be withdrawn.

***Rejection under 35 U.S.C. § 102***

The Examiner rejects claims 1-4, 7, 10-11, 14-16, 30-36, and 40-41 under 35 U.S.C. § 102(e) for allegedly being anticipated by Osumi '292 (U.S. Patent 6,166,292). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

The Osumi '292 patent was filed on April 28, 1997, and issued on December 26, 2000. The 35 U.S.C. § 102(e) date for Osumi '292 is April 28, 1997. In order to overcome this rejection, Applicants prove priority to their own 35 U.S.C. § 119 priority date, which is earlier than Osumi's § 102(e) date.

The present application receives priority under 35 U.S.C. § 119 to Application JP 8-338673 filed in Japan on December 18, 1996. In order to meet the requirements of 37 C.F.R. § 1.55, Applicants file a verified translation of the priority document

JP 8-338673 along with a statement that the translation is correct, attached hereto.

Osumi '292 is no longer available as prior art. Applicants respectfully request withdrawal of the instant rejection.

***Double patenting***

The Examiner provisionally rejects claims 1-4, 6-7, 9-18, 30-36, 40-41, and 43-44 under the doctrine of double patenting for allegedly being unpatentable over claims 1-11 and 16-22 of copending U.S. Application No.: 09/301,766. Claims 1-4, 6-7, 9-18, 30-36, 40-41, and 43-44 are provisionally rejected under the doctrine of double patenting for allegedly being unpatentable over claims 40-49 and 58 of copending U.S. Application No.: 09/415,918. Finally claims 1-4, 7, 10-11, 14-16, 30-36, and 40-41 are provisionally rejected under the doctrine of double patenting for allegedly being unpatentable over claims 5-7 and 14-17 of copending U.S. Application No.: 09/612,095. Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

First, Applicants point out that U.S. Application No.: 09/415,918 has been abandoned. Therefore the rejection of claims 1-4, 6-7, 9-18, 30-36, 40-41, and 43-44 under the doctrine of double patenting for allegedly being unpatentable over said application is rendered moot. Withdrawal of the rejection is respectfully requested.

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Second, Applicants will file appropriate terminal disclaimers over copending U.S. Application No.: 09/301,766 and copending U.S. Application No.: 09/612,095 once the co-pending applications are allowed by the United States Patent and Trademark Office.

**Conclusion**

Applicants respectfully submit that all of the pending rejections have been addressed and overcome by the above remarks and/or amendments. All of the present claims define patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action on the merits of the present application is thereby requested.

If the Examiner has any questions regarding the above, he is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at the law offices of Birch, Stewart, Kolasch, & Birch, LLP, telephone number 703-205-8000.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of one (1) month to June 6, 2002, in which to file a reply to the Office Action. The required fee of \$110.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees

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required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17;  
particularly, extension of time fees.

Respectfully submitted,

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ATTACHMENTS: VERSION WITH MARKINGS TO SHOW CHANGES MADE  
PENDING CLAIMS (AS AMENDED)  
VERIFIED TRANSLATION OF JP 8-338673

VERSION WITH MARKINGS TO SHOW CHANGES MADE

*IN THE CLAIMS:*

The following claims are amended:

**Claim 1.** (Twice Amended) A nucleic acid isolated from a plant comprising a nucleotide sequence coding for an amino acid sequence of a protein which produces [capable of producing] raffinose by combining a D-galactosyl group through an  $\alpha(1 \rightarrow 6)$  bond with a hydroxyl group attached to the carbon atom at position 6 of a D-glucose residue in a sucrose molecule.

**Claim 30.** (Three Times Amended) A chimera gene comprising: a nucleic acid isolated from a plant comprising a nucleotide sequence coding for an amino acid sequence of a protein which produces [capable of producing] raffinose by combining a D-galactosyl group through an  $\alpha(1 \rightarrow 6)$  bond with a hydroxyl group attached to the carbon atom at position 6 of a D-glucose residue in a sucrose molecule, and a promoter linked thereto.

**Claim 32.** (Three Times Amended) A plasmid comprising a nucleic acid isolated from a plant comprising a nucleotide sequence coding for an amino acid sequence of a protein which produces [capable of producing] raffinose by combining a D-galactosyl group through an  $\alpha(1 \rightarrow 6)$  bond with a hydroxyl group

attached to the carbon atom at position 6 of a D-glucose residue in a sucrose molecule.

**Claim 36.** (Three Times Amended) A method for metabolic modification, which comprises introducing a nucleic acid isolated from a plant comprising a nucleotide sequence coding for an amino acid sequence of a protein which produces [capable of producing] raffinose by combining a D-galactosyl group through an  $\alpha(1 \rightarrow 6)$  bond with a hydroxyl group attached to the carbon atom at position 6 of a D-glucose residue in a sucrose molecule into a host organism or a cell thereof, so that the content of raffinose family oligosaccharides in the host organism or the cell thereof is changed.